

# ***GLOBAL LIQUID BIOPSY MARKET***

## **Market Size & Forecast**



# Liquid Biopsy Market: Accelerated Growth Trajectory

14.8%

Market CAGR

Optimistic growth scenario for liquid biopsy  
and precision diagnostics market

4x

Market Expansion

Potential market size increase over ten years  
under accelerated growth

19.0%

EV Subsegment CAGR

Even faster growth projected for extracellular  
vesicle-based diagnostics

The liquid biopsy and precision diagnostics market is experiencing unprecedented acceleration driven by the paradigm shift toward non-invasive, early-stage cancer detection. This optimistic trajectory significantly outpaces the conservative 6.4% CAGR projected in broader liver cancer diagnostics reports, assuming successful resolution of key barriers including standardization, reimbursement accessibility, and regulatory frameworks.

## EV-Based Market Surge

The **extracellular vesicle (EV) subsegment** represents the fastest-growing sector, projected to reach USD 572.43 million by 2034 from USD 102.13 million in 2024. This explosive growth is fueled by EVs' superior stability and molecular richness compared to circulating tumor DNA or circulating tumor cells.

## Multiomic Advantage

EVs offer unparalleled opportunities for multiomic profiling, combining genomic, proteomic, and metabolomic data in a single diagnostic platform. This comprehensive molecular snapshot enables more precise disease characterization and treatment selection than traditional single-biomarker approaches.

# Market Barriers: Critical Challenges Constraining Growth

Despite promising growth projections, several interconnected factors are significantly constraining the liquid biopsy market's full potential. These barriers span technical, economic, regulatory, and social dimensions, requiring coordinated industry-wide solutions.

## Technical & Regulatory Barriers

- **Lack of standardized protocols** for EV isolation, classification, and biomarker validation impedes clinical adoption
- Regulatory uncertainty and slow approval processes delay commercialization of novel diagnostic tests
- Fragmented R&D efforts and insufficient large-scale clinical validation studies hinder confidence in new platforms
- Data privacy concerns and algorithmic bias in AI-driven diagnostics reduce trust among healthcare providers

## Economic & Access Challenges

- **High diagnostic costs** and limited reimbursement policies restrict accessibility, especially in emerging economies
- Elevated R&D expenses and complicated regulatory pathways create significant barriers for new market entrants
- Inadequate healthcare infrastructure in rural and low-income regions limits deployment of advanced diagnostic technologies
- Competition from established methods like ultrasound and AFP testing maintains clinical status quo despite low sensitivity

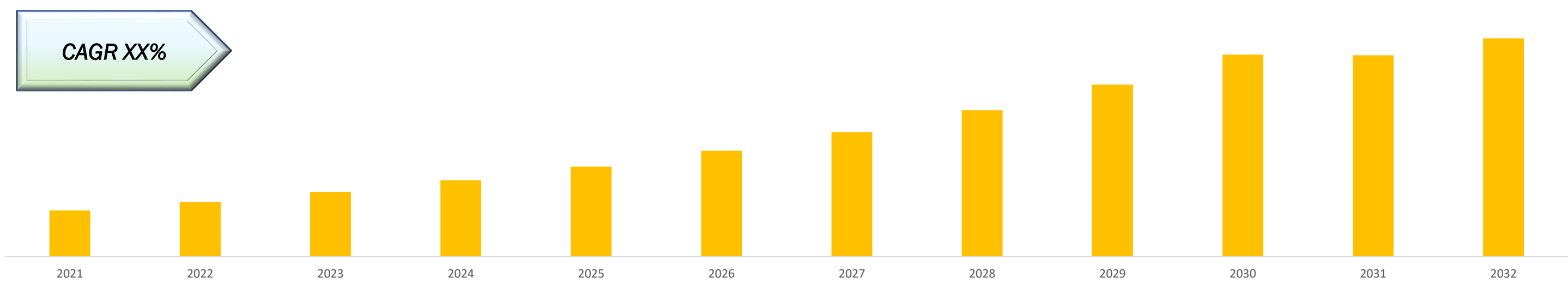
## Clinical & Social Barriers

- **Limited provider awareness** and lack of trained specialists in precision medicine slow clinical integration
- Patient hesitancy due to fears of genetic discrimination or misunderstanding of liquid biopsy benefits
- Workflow integration challenges in existing clinical practice patterns and electronic health record systems

❏ Addressing these multifaceted barriers requires coordinated efforts across industry stakeholders, regulatory bodies, healthcare systems, and patient advocacy groups to unlock the market's full potential.

# Global Liquid Biopsy Market Size & Forecast

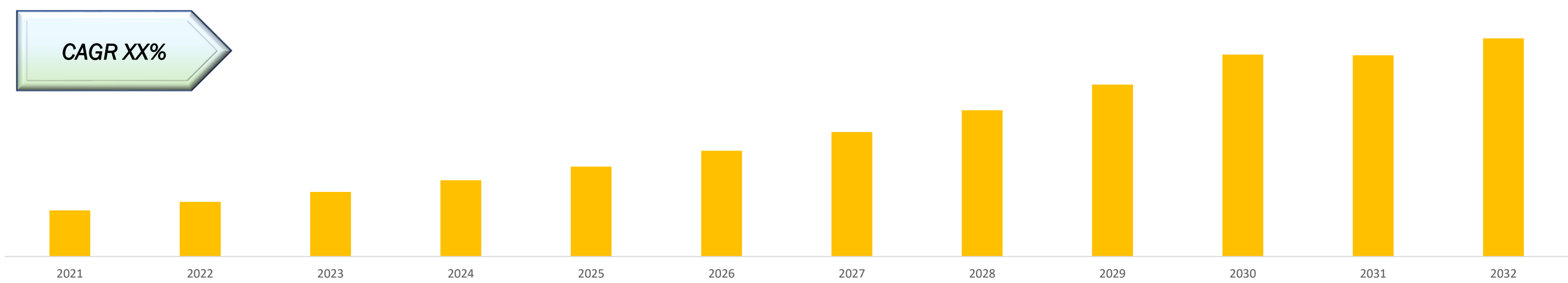
- Global Liquid Biopsy Market Size, 2021-2032



- The escalating cost of fuel has made gasoline-powered two-wheelers increasingly expensive to operate. This economic pressure is a paramount driver for the adoption of electric scooters (E2Ws), which offer significantly lower running costs.
- In India, where two-wheelers make up over 70% of the vehicle fleet, the combination of rising fuel prices, lower operating costs, and government subsidies through programs like FAME-II has made E2Ws a financially compelling choice for both individual consumers and the rapidly growing last-mile delivery sector.
- Fleet operators, in particular, are prioritizing E2Ws for their high mileage and lower cost per kilometer.

# Regional Liquid Biopsy Market Size & Forecast

- Regional Liquid Biopsy Market Size, 2021-2032



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# Regulatory Landscape

## FDA Approvals and Compliance Status

### Current FDA-Approved Liquid Biopsies:

The FDA has approved Guardant360 CDx and FoundationOne Liquid CDx as comprehensive genomic profiling tests for all solid tumors. Guardant360 CDx serves as a companion diagnostic for multiple therapies including osimertinib (TAGRISSO) for lung cancer and elacestrant (ORSERDU) for breast cancer with ESR1 mutations.

**Breakthrough Achievement:** In July 2024, Guardant Health's Shield blood test became the first FDA-approved liquid biopsy for primary cancer screening, specifically for colorectal cancer in adults aged 45 and older. This landmark approval validates the clinical utility of liquid biopsies beyond therapy selection.

### EU IVDR Compliance and International Access

Guardant Health received EU IVDR certification for Guardant360 CDx in 2024, enabling broad access across European markets for comprehensive genomic profiling. The certification covers companion diagnostic indications for lung cancer therapies (TAGRISSO, RYBREXANT, LUMYKRAS) and advanced breast cancer treatment (ORSERDU).

**Regulatory Framework Development:** The FDA convened a Molecular and Clinical Genetics Panel in November 2023 to establish design guidelines for MCED tests, addressing study designs and outcomes for assessing benefits and risks. The panel recommended a three-stage approval system:

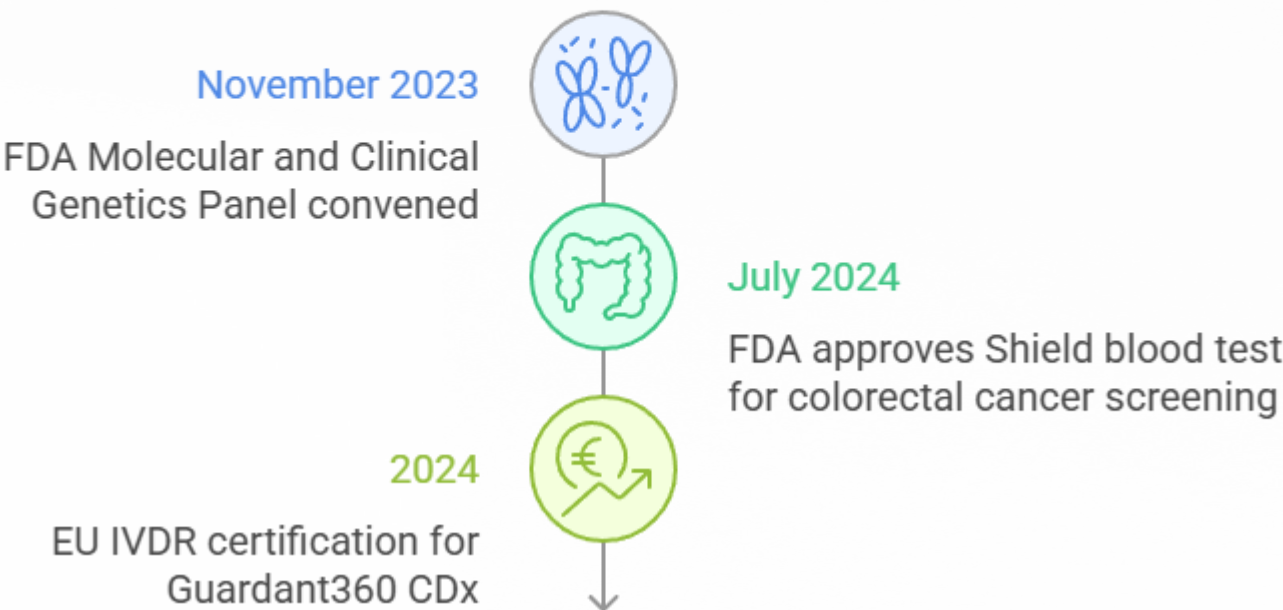
Stage 1: Case-control studies for analytical validation

Stage 2: Single-arm trials for clinical validation in intended populations

Stage 3: Randomized controlled trials demonstrating mortality reduction

The FDA has proposed expanded oversight of LDTs through a risk-based framework similar to commercial IVDs. This change may increase regulatory burden but provides clearer approval pathways and could enhance clinical confidence in liquid biopsy testing.

## Key Regulatory Milestones in Liquid Biopsy Development



# Reimbursement Landscape

## Reimbursement Challenges and Coverage Status

### Medicare Coverage Breakthrough

Guardant Shield received Advanced Diagnostic Laboratory Test (ADLT) status from CMS with a \$1,495 reimbursement rate beginning April 2025. This rate applies during the initial nine-month period, after which CMS will determine pricing based on private payer data.

The ADLT designation confirms that Shield provides unique clinical information unavailable through other methods, establishing favorable reimbursement precedent for innovative liquid biopsy screening applications.

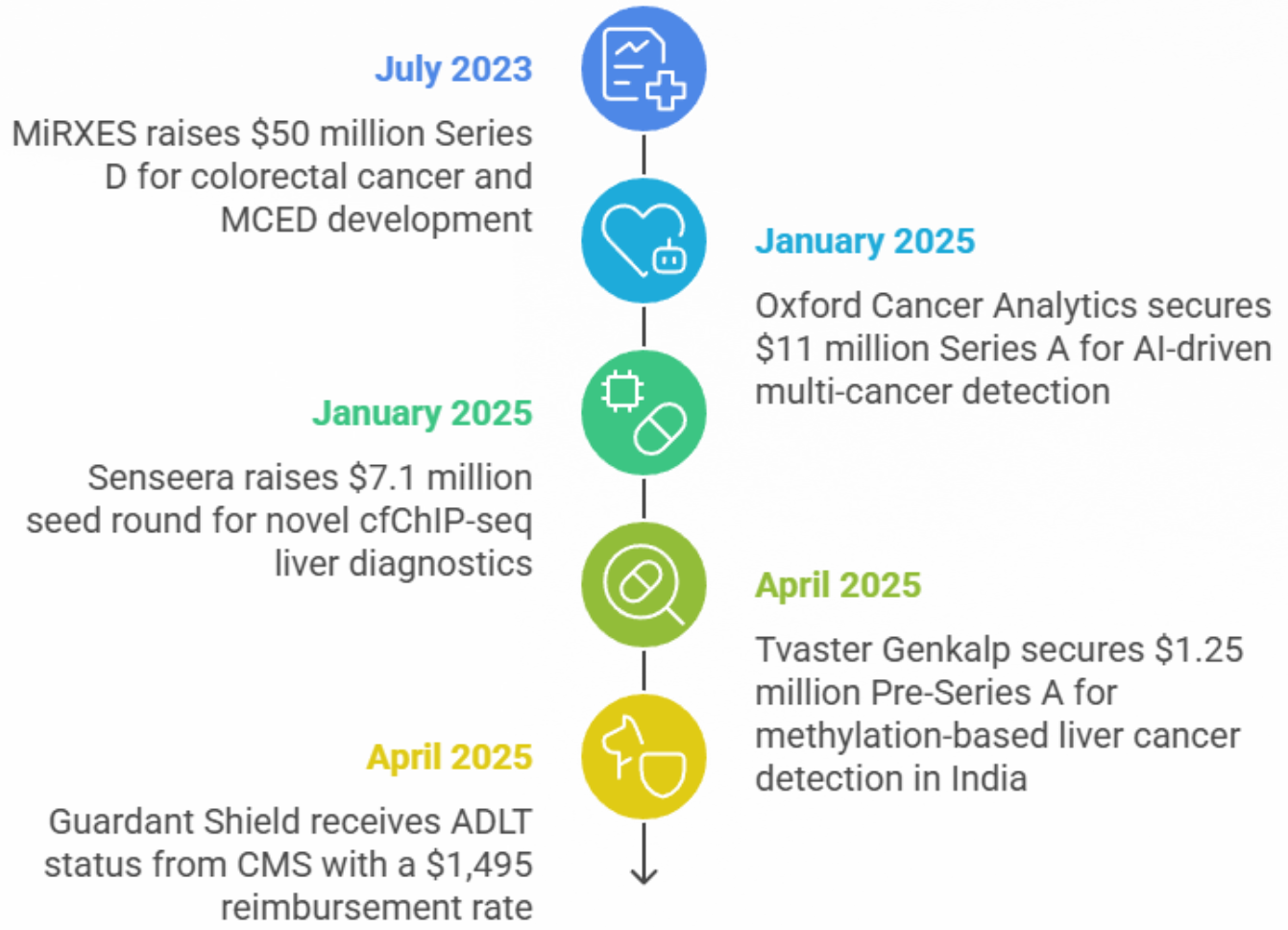
### Venture Capital Investment Surge

\$7.3 billion has been invested in liquid biopsy companies globally from 2020-2024, with the majority raised through venture funding rounds.

### Notable Recent Investments:

- GRAIL: \$1.214 billion (largest liquid biopsy investment establishing the MCED category)
- MiRXES: \$50 million Series D (July 2023) for colorectal cancer and MCED development
- Oxford Cancer Analytics: \$11 million Series A (January 2025) for AI-driven multi-cancer detection
- Senseera: \$7.1 million seed round (January 2025) for novel cfChIP-seq liver diagnostics
- Tvaster Genkalp: \$1.25 million Pre-Series A (April 2025) for methylation-based liver cancer detection in India
- European Union Horizon Europe: €150-250 million supporting liquid biopsy standardization and cross-border regulatory harmonization.

## Advancements in Liquid Biopsy Reimbursement and Investment



# Competitive Landscape: Market Leaders in EV Diagnostics

The EV-based liquid biopsy market is characterized by **established diagnostics giants** leveraging extensive R&D capabilities and global distribution networks alongside innovative emerging players focused on specialized applications.



## Thermo Fisher Scientific

Comprehensive molecular diagnostics portfolio including sequencing platforms essential for liquid biopsy workflows. Market leader in sample preparation and analysis instrumentation.



## Qiagen N.V.

Specialized sample preparation kits and advanced bioinformatics solutions specifically designed for EV isolation and comprehensive molecular analysis.



## Bio-Techne Corporation

Leading provider of EV isolation kits and sophisticated immunoassay tools for precise biomarker detection and quantification.

## Analytical Instrumentation Leaders

- Horiba Ltd. - Advanced analytical instruments for comprehensive EV characterization and quality control
- Malvern Panalytical Ltd. - Cutting-edge particle analysis systems for precise EV size distribution and concentration measurement

## Specialized Service Providers

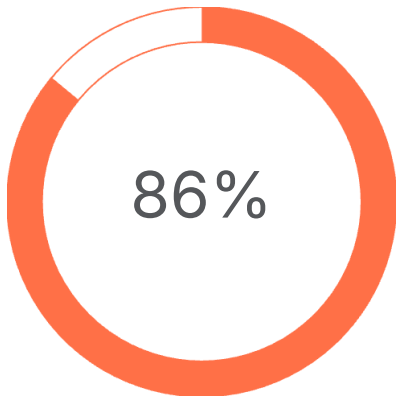
- Lonza Group AG - Contract development and manufacturing services for EV-based therapeutics and diagnostic applications
- Norgen Biotek Corp. - Comprehensive EV isolation kits and specialized services for research and clinical applications

These established players dominate through **scale advantages, regulatory expertise, and comprehensive product ecosystems**, while creating opportunities for specialized innovators to capture niche segments through breakthrough technologies and focused clinical applications.



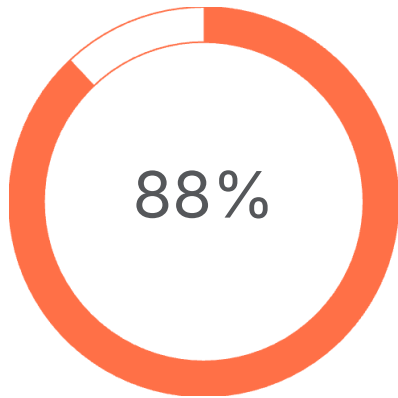
# Mursla Bio: Pioneering AI-Driven EV Diagnostics

Mursla Bio emerges as a **transformative innovator** in the EV-based liquid biopsy landscape, distinguished by its proprietary AI Precision Medicine Platform and groundbreaking organ-specific EV isolation technology. Unlike generalist competitors, Mursla’s approach centers on biologically labeled, tissue-specific datasets that enable unprecedented diagnostic precision.



Sensitivity Rate

EvoLiver™ performance in early-stage liver cancer detection among high-risk cirrhotic patients



Specificity Rate

Demonstrated accuracy in distinguishing cancer from benign liver conditions

## Flagship Innovation: EvoLiver™

The company’s breakthrough diagnostic platform achieved remarkable clinical performance with 86% sensitivity and 88% specificity in detecting early-stage liver cancer among high-risk cirrhotic patients. This performance significantly exceeds current standard-of-care methods and earned **FDA Breakthrough Device Designation in April 2025**, accelerating clinical adoption pathways.

Mursla’s strategic involvement in global standardization efforts, including participation in the EVEREST European consortium, positions the company as a key contributor to advancing EV-based diagnostic standards across the industry.

## Strategic Market Position

Operating from **Cambridge, UK and Boston, MA**, Mursla leverages proximity to world-class academic institutions and pharmaceutical partners. The company’s dual-hub strategy facilitates transatlantic collaborations and access to diverse patient populations for clinical validation.

Beyond liver cancer, Mursla’s AI-powered patient stratification platform offers scalable applications across cardiometabolic and other oncology indications, creating multiple revenue streams and market expansion opportunities.

## Direct EV Competitors

- Nanostics Inc. - EV-based liquid biopsy for prostate cancer detection
- Mercy BioAnalytics - Metabolomic profiling of EVs for disease detection
- Clara Diagnostics - EV-based early cancer detection platforms

# Strategic Outlook: Unlocking Multi-Billion Dollar Potential

Achieving the projected **14.8% CAGR or higher** requires coordinated industry transformation across multiple dimensions. Success depends on resolving fundamental barriers while capitalizing on emerging opportunities in precision medicine and AI-driven diagnostics.



## Industry Standardization

Establish unified protocols for EV isolation, biomarker validation, and quality control to enable widespread clinical adoption and regulatory approval acceleration.



## Cost Optimization & Access

Reduce diagnostic costs through technological innovation and manufacturing scale while expanding reimbursement coverage to democratize access across diverse populations.



## Clinical Validation

Conduct large-scale, multi-population studies to validate clinical utility and build healthcare provider confidence in EV-based diagnostic platforms.



## Healthcare Integration

Enable routine integration of EV-based tests into primary care workflows, transforming cancer surveillance from reactive imaging to proactive blood-based monitoring.

## Market Transformation Vision

The successful resolution of current barriers will catalyze a fundamental shift in cancer care delivery. **Proactive blood-based monitoring** will replace reactive imaging-based detection, enabling earlier intervention and improved patient outcomes while reducing healthcare system costs.

This transformation creates opportunities for longitudinal patient monitoring, personalized treatment selection, and AI-powered risk stratification that extends far beyond traditional diagnostic applications.

"The convergence of AI, extracellular vesicle biology, and precision medicine represents the most significant diagnostic revolution since the advent of molecular testing, with the potential to transform healthcare delivery on a global scale."

## Multi-Billion Dollar Ecosystem

Success in addressing these challenges will unlock a **multi-billion dollar diagnostic ecosystem** encompassing not only cancer detection but comprehensive disease monitoring, treatment response assessment, and precision medicine applications across multiple therapeutic areas.

For Mursla Bio and similar innovators, this represents an unprecedented opportunity to establish market leadership in the next generation of precision diagnostics.